

Adult CIRB - Early Phase Emphasis Meeting Agenda

April 2, 2024

I Amendment

10301, A Phase I and Randomized Phase II Trial of Radium-223 dichloride, M3814, & Avelumab in Advanced Metastatic Castrate-Resistant Prostate Cancer (mCRPC) (Version Date 02/13/24)

II Amendment

10144, A Phase II Study of Olaparib (AZD2281) in Patients with Metastatic/Advanced Urothelial Carcinoma and other genitourinary tumors with DNA-Repair Defects (Version Date 02/28/24)

III Amendment

EAY191-N2, A ComboMATCH Treatment Trial EAY191-N2: Phase 2 Trial of Fulvestrant and Binimetinib in Patients with Hormone Receptor-Positive Metastatic Breast Cancer with Inactivating or Inferred Inactivating NF1 Alterations (Version Date 02/12/24)

IV Continuing Review

10401, A Phase 0 window-of-opportunity pharmacodynamic trial of triapine (NSC# 663249) in uterine corpus serous adenocarcinoma (Version Date 08/15/23)

V Continuing Review

10302, Phase II Trial of Radium-223 Dichloride in Combination with Paclitaxel in Patients with Bone Metastatic Breast Cancer (Version Date 08/07/23)



VI Continuing Review

10291, A Phase 1b Study of Berzosertib in Combination with Radiation Therapy to Overcome Therapeutic Resistance in Chemotherapy Resistant Triple Negative and Estrogen and/or Progesterone Receptor Positive, HER2 Negative Breast Cancer (Version Date 09/16/22)

VII Continuing Review

10186, A Phase I/II Study of Nivolumab plus or minus Ipilimumab in Combination with Multi-fraction Stereotactic Radiosurgery for Recurrent Highgrade Radiation-relapsed Meningioma (Version Date 01/08/24)

VIII Continuing Review

10464, A Phase 1 Study of Olaparib in Combination with Durvalumab (MEDI4736) and Concurrent Radiation Therapy Following First-Line Chemotherapy in Locally Advanced Unresectable Pancreatic Cancer (Version Date 11/03/23)